UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,068	09/20/2001	Hazire Oya Alpar	41577/263898	6302

23370 7590 05/19/2005

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,068	ALPAR ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-10 and 12-32* is/are pending in the application.

4a) Of the above claim(s) *14-28 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-10,12,13 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 9/20/01 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2004 has been entered.

Election/Restrictions

2. Newly submitted claims 27-28 and 30-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to non-elected species which are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Similarly, claim 26 is also drawn to a non-elected species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-28 and 30-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Amendment Entry

3. The amendment filed March 1, 2005 has been entered. The amendment filed January 25, 2005 has not been entered for reasons already of record. Claims 1, 4,6-8 and 26 have been amended. Claims 2 and 11 have been cancelled. Claims 14-28 and 30-32 have been withdrawn from consideration. Claims 1, 3-4, 6-10, 12-13 and 29 drawn only to positively charged cationic block copolymers or positively charged cationic surfactants are under consideration in this office action.

Withdrawal of Objections and Rejections

4. The following objections and rejections have been withdrawn:

a) The objection of claim 4 is withdrawn in view of applicants' amendment;

b) The rejection of claim 4 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicants' amendment; and

c) The rejection of claims 10 and 13 under 35 U.S.C. 102(e) as being anticipated by Griffin et al., (1998) is withdrawn in view of applicants' arguments.

Response to Arguments

5. Applicant's arguments filed March 1, 2005 have been fully considered but are not found persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 1, 3-4, 6-9,12-13 and 29 under 35 U.S.C. 102(b) as being anticipated by Duncan et al., (WO 94/20070 published September 15, 1994) is maintained for reasons already of record. The rejection was on the grounds that Duncan et al., taught a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid.

Applicants' argue that Duncan et al., do not disclose using particulate vaccines with the claimed adjuvants. However, Duncan et al., clearly recite that the vaccine compositions can be prepared in dosage units suitable for oral administration, such as particles, granules, beads, and capsules (page 11, para. 4). Duncan et al., further state that the immunization composition can be treated to protect the antigen, adjuvant and mucoadhesive from degradation by using conventional methods such as creating emulsions or microencapsulation techniques (pages 11-12, para. 5-1). Therefore, Duncan et al., clearly disclose a vaccine composition comprising pharmaceutically acceptable particles wherein the particles comprise a biologically active agent such as an antigen and an adjuvant contrary to applicants' statements.

Applicants' assert that Duncan et al., disclose that instead of using particles, one could utilize mucoadhesives and that the disclosure should be read in that light. However applicants' have misconstrued the teaching of Duncan et al. Applicants' point to page 14, lines 14-18 as evidence that Duncan et al., teach away from the use of particles, however, this section refers to the components of the composition and not to the structure and delivery system of the composition. Therefore applicants' assertions are not persuasive. Page 14, lines 14-18 from Duncan simply recite a bare minimum of components that can be included in the composition. Pages 11-12, para. 5-1, teach the delivery system and structure of such compositions as being pharmaceutically acceptable particles that are microcapsules or liposomes. Duncan et al., clearly state that the composition should be protected from degradation by providing that the recited ingredients be comprised within liposome emulsions or microencapsulated form.

Moreover, the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). In this case, Duncan et al.,

clearly teach vaccine compositions comprising pharmaceutically acceptable particles wherein the particles comprised a biologically active agent and an adjuvant contrary to applicants' statements. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

7. The rejection of claims 1, 3-4, 6-9,12 and 29 under 35 U.S.C. 102(a) as being anticipated by Griffin et al., (1998) is maintained for reasons already of record. The rejection was on the grounds that Griffin et al., taught a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid.

Applicants' assert that the poly(L)lactide as disclosed by Griffin et al., does not fall within the definitions of a positively charged cationic block copolymer or positively charged cationic surfactant which is positively charged by means of NH_2^+ groups. However, poly(L)lactide are highly positively charged block copolymers which comprise amine groups on its side chains. Therefore, contrary to applicants' statements, poly(L)lactide is encompassed within the class of adjuvants drawn to positively charged cationic block copolymer which do not

contain a polyacrylic acid. Thus poly(L)lactide falls within the definition of the instantly claimed class of adjuvants, contrary to applicants' statements. Thus the rejection is maintained.

8. The rejection of claims 1, 3-4, 6-10,12-13 and 29 under 35 U.S.C. 102(e) as being anticipated by Park et al., (US Patent 6,267,987 Published July 31, 2001 with an earlier filing date of December 11, 1998) is maintained for reasons already of record. The rejection was on the grounds that Park et al., taught a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid.

Applicants' assert that certain block copolymers are all purpose carriers and that no adjuvant or immunostimulant properties are disclosed in the reference. However, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) which state "[T]he fact that a characteristic is a necessary feature or

result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention." Therefore, the immunostimulant properties which applicants' refer to are an inherent property of the positively charged cationic block copolymer or a positively charged cationic surfactant which do not contain a polyacrylic acid. Therefore, Park et al., is not required to teach the inherent immunostimulant properties of the copolymers to meet the limitations of the claims. Rather the requirement is that Park et al., disclose those copolymers, which Park et al., does. Therefore, the copolymers of Park et al., meet the instantly claimed limitations and applicants' assertions are irrelevant.

Applicants' assert that the block co-polymers described in Park et al., fail to fall within the claimed class of adjuvants. However Park et al., teach compositions comprising a block copolymer of poly(L-lactide) coupled with poly[α ω-aminoalkyl) glycolic acid (col. 3-4, lines 65-19). These copolymers are cationic block copolymers positively charged by means of NH_2^+ amine groups thereby meeting the limitations of the claims. Moreover, Park et al., teach that such copolymers can be prepared as di-, tri-, or multi-block copolymers (col. 8, lines 21-23). The polymers taught by Park et al., have the recited properties of being positively charged by means of NH_2^+ amine groups cationic block copolymer which do not contain a polyacrylic acid. Therefore the copolymers are encompassed within the class of adjuvants instantly claimed, contrary to applicants' arguments.

Applicants' assert that the complexes of Park et al., fall to have a defined microcapsule or liposome structure as recited by the claims. However, Park et al., state that it is well known to deliver compositions comprising these polymers in the form of microspheres (col. 1-2, lines 66-1). Moreover, Park et al., teach providing compositions delivered within particles, nanospheres, and microspheres (col. 7 lines, 51-55). Park et al., also teach that nanoparticles or microspheres can be conjugated with the copolymers as exemplified by Figure 4 which shows an illustrative nanoparticle loaded with a drug. The matrix of the nanoparticle is composed of copolymers such as polylactic-glycolic acid and poly[α ω-aminoalkyl) glycolic acid which create a positively charged surface due to the cationic nature of the poly[α ω-aminoalkyl) glycolic acid (col. 9, lines 9-14). Therefore, despite applicants' arguments to the contrary, Park et al., clearly meet the limitations of the instant claims, since Park et al., clearly teach compositions having defined microcapsule or liposome structures. Therefore, applicants' arguments are not persuasive and the rejection is maintained.

New Grounds of Objection

Specification

9. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If

no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

10. The instant specification fails to include a section drawn to the Brief Description of Drawings. See M.P.E.P section 37 CFR 1.74 entitled Reference to drawings. When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the

different parts by use of reference letters or numerals (preferably the latter). Therefore clarification is required to overcome the objection.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

12. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires that an adjuvant chemical act as an immunostimulant, however claim 3 is drawn to the adjuvant chemical acting as an immunostimulant. Thus, claim 3 fails to further limit claim 1.Therefore, clarification is required to overcome this objection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Written Description

13. Claims 1, 3-4, 6-10, 12-13 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid.
The claims are so broad that they encompass every type of vaccine and biologically active agent which effects all types of diseases, disorders and infections in any type of animal.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the

application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where

there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli,* the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a vaccine composition comprising pharmaceutically acceptable particles wherein the particles comprised a biologically active agent in combination with an adjuvant chemical. The generic statements drawn to the vaccine composition and biologically active agent do not provide ample written description for the compounds since the claims do not describe a singe structural feature associated with the biologically active agent. The specification does provide examples of what qualify as compounds of the claimed invention. However, these examples are limited to a sub-unit vaccines such as *Yesinia pestis, Bacillus anthracis*, diptherеria toxoid

and tetanus toxoid, see page 11, lines 6-19 of the instant specification. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

The instant specification fails to provide any experiments that show that such vaccines would be effective in protecting an animal against any type of infection. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to a bacterial infection or disease induction. More importantly, there are no challenge experiments to demonstrate that an animal immunized with the claimed vaccine that would be protected from any type infection. There is no disclosure that demonstrates how the vaccine comprising the broadly defined biologically active agent would be effective in immunization, nor are their protocols detailing the amount of biologically active agent needed to

mount a sufficient immune response. There is merely a general outline of vaccines that do not apply directly to the instant invention. Moreover, the specification discloses that immune responses, i.e., elevated antibody levels, were generated in mice, however it is well known that merely generating an immune response does not equate to providing protective immunity. Thus the specification fails to provide an adequate written description of a vaccine comprising an undisclosed biologically active agent and adjuvant that will provide protective immunity to all types of infections and diseases.

This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing any type infection or disease. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The specification fails to teach the identity a vaccine with the claimed characteristics. Furthermore, the specification fails to adequately disclose a description of the claimed vaccines, thus a skilled artisan would be required to de novo locate, identify and characterize the claimed vaccines and biologically active agent with the recited abilities.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. In view of these considerations, a person skilled in the art would not have viewed the

teachings of the specification sufficient to show that applicants were in possession of a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprised a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter

14. Claims 1, 3-4, 6-10, 12-13 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provide support for a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an

adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid.

Applicants' did not point to support in the specification for a vaccine composition comprising pharmaceutically acceptable particles which encompass an undisclosed biologically active agent in combination with an adjuvant chemical. There appears to be no teaching of a generic vaccine composition which could treat all infections and diseases. Thus, it appears that the entire specification appears to fail to recite support for the newly recited vaccine composition with the ability to provide protective immunity to any and/or all infections and/or diseases. Therefore, applicants' must specifically point to page and line number support for a vaccine composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes wherein the particles comprise a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being a positively charged cationic block copolymer or a positively charged cationic surfactant which does not contain a polyacrylic acid as recited by the amended claims. Therefore, the claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 112 2nd paragraph

15. Claims 1, 3-4, 6-10, 12-13 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 recites alternative limitations with respect to the adjuvants which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

b) Claim 1 recites the term microcapsules, while dependant claims 8 and 10 recite the term microspheres. It appears that applicant is referring to the same type of particle, therefore, it is requested that consistent terminology be used throughout the claims.

c) Claims 8 and 10 recite the limitation "the microspheres" in the claims. There is insufficient antecedent basis for this limitation in the claim.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on7. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

May 5, 2005